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REMARKS

Status Summary

Claims 1-30 were pending in the present application as originally filed. The U.S. Patent and Trademark Office (hereinafter "the Patent Office") had restricted the pending claims to five groups. Applicants elected Group I drawn to a method for "capturing one or more target simple sequence repeats", including Claims 1-8 and 11-24. Applicants further elected distinct species within Group I, as required by the Patent Office. Applicants also added new Claim 31 as part of the Response to the Restriction Requirement.

In the present Official Action, the Patent Office has further withdrawn Claims 16, 17, 22, and 31 from the elected group of claims, alleging these claims do not read on the elected species. As set forth in detail below, applicants respectfully traverse the Patent Office's withdrawal of Claims 22 and 31 and request these claims be returned to pending status along with the remaining Claims 1-8, 11-15, 18-21 and 23-24, which the Patent Office indicates have been examined on the merits in the present Official Action.

The Patent Office has also rejected Claims 1, 7, 11, and 24 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Further, the Patent Office has rejected Claims 1-8, 12-15, 18-21, 23-24 and 31 under 35 U.S.C. § 103(a) as being unpatentable over a combination of cited art references.

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Applicants have amended Claims 11, 22, and 24 to more particularly claim the presently disclosed subject matter. No new matter has been added by these Amendments. In consideration of the present U.S. patent application as amended and based on the arguments set forth herein.

Restriction and Election of Species

In the present Official Action, the Patent Office has further withdrawn Claims 16, 17, 22, and 31 from the elected group of claims, alleging these claims do not read on the elected species.

With regard to Claim 22, the Patent Office argues the claim does not read on the elected "Subgroup IV = streptavidin" species because streptavidin is not listed in the Markush Group recited in Claim 22. As indicated above, Claim 22 has been amended to more particularly claim the subject matter. The word "avidin" has been replaced with "streptavidin" by the claim amendment. Support for the amendment can be found in the specification at p. 14, lines 3-11. Claim 22 as corrected now recites the Markush Group to include streptavidin. As such, Claim 22 does read on the elected Subgroup IV, as it includes streptavidin as intended. Therefore, applicants respectfully request the Patent Office reinstate Claim 22 to pending status.

With regard to Claim 31, the Patent Office asserts Claim 31 does not read on the elected species wherein "all the nucleotides are LNA" because, as alleged by the Patent Office, Claim 31 recites that only the first G is an LNA. Applicants wish to clarify the Patent Office's understanding of Claim 31. Claim 31 recites that the target

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simple sequence repeat is -5'-(CA)₆-3', wherein the modified oligonucleotide conjugate is 3 biotinylated (GT)₆-5' bicyclic structure, wherein the LNA occurs on the first G, and wherein the target source is a plasmid library. The phrase "wherein the LNA occurs on the first G" only indicates that the first G comprises an LNA, and does not mandate any characteristics for the remaining nucleotides. Therefore, a modified oligonucleotide wherein all the nucleotides are LNA is encompassed by the scope of Claim 31 so long as at least the first G is an LNA. As such, applicants respectfully submit Claim 31 does read on the elected species, and therefore applicants request the Patent Office reinstate the pending status of Claim 31.

Claim Rejection - 35 U.S.C. § 112

The Patent Office has rejected Claims 1, 7, 11, and 24 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Patent Office has rejected Claims 1 and 7 under 35 U.S.C. § 112, second paragraph, for reciting "substantially", which the Patent Office regards as a relative term rendering these claims indefinite and/or unclear. The Patent Office argues the term is not defined by the claim, or the specification and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicants respectfully traverse the Patent Office on this rejection. One of skill in the art will appreciate that in the milieu of a biochemical reaction, a reaction in practice rarely, if ever, goes to absolute completion. Therefore, one of skill in the art

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would clearly understand what was meant by “substantially all” as recited in Claims 1 and 7 within the context of a biochemical reaction, as encompassed by the pending claims. See *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988), and MPEP 2173.05 (b) (D). Therefore, applicants respectfully request withdrawal of the rejection of Claims 1 and 7 under 35 U.S.C. § 112, second paragraph.

The Patent Office has also rejected Claim 7 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Patent Office argues that it is not clear what “reaction conditions” promote the formation of an “A helix”, therefore rendering Claim 7 indefinite. Applicants respectfully traverse this rejection. One of ordinary skill in the art would have a clear understanding of the critical parameters for determining the reaction conditions to promote the formation of an A helix after reading the specification. Specifically, beginning at page 13, line 17 of the specification, it is taught that an A helix forms due to hybridization of the LNA conjugate and target SSR. The specification further teaches that LNAs duplexed with a complementary target SSR occurs at higher annealing temperatures and have higher thermal stabilities than corresponding DNA or RNA duplexes. The specification teaches that these annealing temperature differences provide an advantage over prior art methods. Further, at page 7, line 18, the specification discusses in detail what is meant by the term “hybridization” as used in the present application. Finally, the Example set forth in the specification provides exemplary reaction conditions to promote hybridization and subsequent formation of an A helix as one non-limiting

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example for one of skill in the art to follow when determining proper reaction conditions under individual circumstances. Therefore, applicants respectfully submit the term "reaction conditions" as set for in Claim 7 is not indefinite and respectfully request withdrawal of the rejection of Claim 7 under 35 U.S.C. § 112, second paragraph.

The Patent Office has rejected Claim 11 under 35 U.S.C. § 112, second paragraph, as being indefinite because the element "the insert in the 3.5kb clone" has insufficient antecedent basis. Applicants have amended Claim 11 to correct the antecedent basis by replacing the pronoun "the" before "insert" and "3.5kb clone" with "an" and "a", respectively. Applicants therefore respectfully request withdrawal of the rejection of Claim 11 under 35 U.S.C. § 112, second paragraph.

The Patent Office has rejected Claim 24 under 35 U.S.C. § 112, second paragraph, as being indefinite, alleging the element "the linking molecule biotin" and "the modified oligonucleotides" have insufficient antecedent basis. Applicants have amended Claim 24 to correct the inadvertent typographical error. As such, applicants believe the elements "the linking molecule biotin" and "the modified oligonucleotide conjugates" recited in Claim 24 now have proper antecedent basis. Therefore, applicants respectfully request withdrawal of the rejection of Claim 24 under 35 U.S.C. § 112, second paragraph.

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Claim Rejection - 35 U.S.C. § 103(a)

Claims 1-8, 12-15, 18-21, 23, 24, and 31 stand rejected by the Patent Office under 35 U.S.C. § 103(a) as being unpatentable over U.S. Published Application No. 2003/0077609 A1, claiming priority to U.S. Provisional Patent Application No. 60/278,598, both to Jakobsen et al. (hereinafter referred to as "Jakobsen et al.") in view of the journal article to Cregan et al. (*Theor. Appl. Genet.* **1999**, 98: 919-928, hereinafter referred to as "Cregan et al."); the publication of Sambrook et al. (*Molecular Cloning: A Laboratory Manual* 2001, New York: Cold Spring Harbor Laboratory, Vol. 2; 11.35 and 11.98-11.106, hereinafter referred to as "Sambrook et al."); and the publication of Brown (*Genomes* 1999, New York: John Wiley & Sons, Inc., pp. 18-23 and 136-137, hereinafter referred to as "Brown").

Regarding Claim 1, the Patent Office argues that Jakobsen et al. discloses methods of using modified LNAs for the isolation, purification, amplification, detection, identification, quantification, or capture of nucleic acids including applications in gene mapping and/or genotyping. The Patent Office argues this asserted disclosure by Jakobsen et al. reads on Claim 1. See Official Action at pp. 8-9. However, the Patent Office admits that Jakobsen et al. does not teach or suggest utilizing LNAs in a method for capturing target simple sequence repeats (SSR), as recited in independent Claims 1 and 24. The Patent Office then asserts that Cregan et al., Sambrook et al., and Brown teach the use of SSRs as target molecules, and that it would have been obvious to one of skill in the art to combine the teachings of

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Jakobsen et al. with Cregan et al., Sambrook et al., and Brown to render the invention as recited in Claims 1 and 24 obvious.

The positions of the Examiner as summarized above with respect to the pending claims are respectfully traversed as described below.

To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art references when combined. See *In re Royka* 490 F.2d 981, 180 USPQ 580 (CCPA 1974). In response to the above-discussed rejection based on 35 U.S.C. § 103(a), applicants respectfully submit the attached Declaration under 37 CFR § 1.131 as Exhibit A. Summarily, the attached Declaration establishes that the inventive subject matter of the currently pending claims was invented prior to the earliest effective priority date of Jakobsen et al., which is March 25, 2001. Consequently, it is respectfully submitted that Jakobsen et al. cannot properly be relied upon as a prior art reference against the presently pending claims.

The Patent Office relies upon Jakobsen et al. as a reference to teach using modified LNAs for the capture of nucleic acids. None of the remaining references Cregan et al., Sambrook et al., and/or Brown, teach, alone or in combination, the use of LNAs for the capture of target SSRs. As such, applicants respectfully submit none of the remaining references cited by the Patent Office specifically teach or suggest all the claim limitations of either independent Claims 1 or 24, and therefore Claims 1 and 24 are believed to be patentably distinguished over Cregan et al., Sambrook et al., and/or Brown either alone or in combination. Applicants therefore respectfully

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request withdrawal of the rejection of Claims 1 and 24 based on the cited references. Allowance of Claims 1 and 24 is also respectfully requested.

With regard to the Patent Offices rejection of Claims 2-8, 12-15, 18-21, 23, and 31, applicants contend that none of the remaining cited references, either alone or in combination, teach all the elements of these claims either. Moreover, Claims 2-8, 12-15, 18-21, 23, and 31 depend either directly or indirectly from Claims 1 and 24, and as the remaining cited references of Cregan et al., Sambrook et al., and Brown do not teach or suggest all the elements of Claims 1 or 24 for the reasons stated above, the remaining cited references therefore do not teach or suggest all the elements of these dependent claims either. Applicants therefore respectfully request withdrawal of the rejection of Claims 2-8, 12-15, 18-21, 23, and 31 on the basis of the remaining cited references. Allowance of these claims is also respectfully requested.

Obviousness-Type Double Patenting Rejection

Claims 1-8, 11-15, 18-21, 23, and 24 have been provisionally rejected based upon the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of Published U.S. Patent Application No. 2003/0032028 A1 (referred to herein as the '028 Application), which is a continuation-in-part of the presently pending application. This rejection is respectfully traversed.

In an effort to address this rejection, applicants submit herewith a timely filed Terminal Disclaimer in compliance with 37 C.F.R. §1.321. Please charge the

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\$110.00 large entity fee set forth in 37 C.F.R. §1.20(d) to Deposit Account No. 50-0426.

In submitting the attached Terminal Disclaimer, applicants do not acknowledge that the subject matter recited in the claims of the present application and in claims 1-37 the '028 Application are not patentably distinct. Moreover, applicants do not acknowledge that the subject matter described and claimed in the subject application is an obvious variation of the invention described and claimed in claims 1-37 of the '028 Application. Indeed, the Federal Circuit has noted that a Terminal Disclaimer "is not an admission of obviousness of the later filed claimed invention in light of the earlier filed disclosure for that is not the basis of the Disclaimer." Quad Environmental Technologies v. Union Sanitary District, 20 U.S.P.Q.2d 1392, 1394 (Fed. Cir. 1991).

The Federal Circuit further noted:

In legal principle, the filing of a Terminal Disclaimer simply serves the statutory function of removing the rejection of double patenting and raises neither presumption nor estoppel on the merits of the rejection. It is improper to convert this simple expedient "obviation" into an admission or acquiescence or estoppel on the merit.

Quad Environmental Technologies, 20 U.S.P.Q.2d at 1394-95.

Therefore, with the submission of the Terminal Disclaimer provided herewith, applicants are simply availing themselves of the statutory function of removing the double patenting rejection.

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CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

JENKINS, WILSON & TAYLOR, P.A.

Date: 11/15/2004

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